

The §112 Rejections

The Examiner rejected claims 60, 67, and 73 under 35 U.S.C. §112 ¶2 as being indefinite. Applicants have (1) amended claim 60 to change its claim dependency from claim 56 to claim 58, (2) amended the phrase “with the tube disposed” to “when the tube is received” in claim 67 to emphasize that the means for hingeable movement is being recited; and (3) deleted the word “vertically” in claim 73. These amendments to the claims remove the bases for the rejections without narrowing the scope of the claims. Applicant urges that these claims, as amended, satisfy the provisions of 35 U.S.C. §112 ¶2. Reconsideration and withdrawal of these rejections are respectfully requested.

The §101 Rejections

The Examiner rejected claims 63, 66, and 75 under 35 U.S.C. §101. Applicant is unclear as to the reasons for the Examiner’s rejections. Claim 63, which ultimately depends from claim 55, is directed to an assembly for fixing a tube to a patient’s mouth for medical purposes. Thus, claim 63 is directed to a useful machine, which satisfies the §101 criteria of being a “useful process, machine, manufacture, or composition of matter, or . . . improvement thereof”. Claim 63 is further directed to limiting the slots of claim 57. Since the slots are part of an assembly intended for use with a patient’s mouth, it is reasonable to describe the slots with reference to their intended use, namely securing the assembly around a patient’s head. Thus, the phrase “wherein the slots are disposed at a level with corners of a jaw of the patient” in original claim 63 is a limitation on the slots, not, for example, a claim to the patient’s jaw.

Similarly, claim 66, which also ultimately depends from claim 55, is directed to an assembly for fixing a tube to a patient’s mouth for medical purposes, and is further directed to limiting the cap claimed in claim 64. Since the cap is intended for placement over a patient’s head, to claim the cap as extending over the patient’s head is to limit the cap, not to claim the patient’s head.

Finally, claim 75 is further directed to limiting the positioning plate claimed in claim 56. Since the positioning plate is an element of an apparatus intended for fixing a tube to a patient’s mouth, it is reasonable to describe it with reference to a patient’s face.

Notwithstanding the above, Applicant has now amended claims 63, 66, and 75 to more clearly indicate that the patient is not being claimed. Since all of the language in claims 63, 66, and 75 serves to limit an element of the claimed apparatus, and not to claim a patient or any part thereof, claims 63, 66, and 75 are all directed to statutory subject matter under 35 U.S.C. §101. Reconsideration and withdrawal of these rejections are respectfully requested.

The §102 Rejections

The Examiner rejected claims 55-56, 67-70, 75, 81, and 84-85 under 35 U.S.C. § 102(b) as being anticipated by United States Patent No. 5,555,881 (Rogers, *et al.*). The Examiner further rejected claims 55-56, 67-71, 75, and 81-84 under 35 U.S.C. § 102(b) as being anticipated by United States Patent No. 4,249,529 (Nestor, *et al.*).

Applicant respectfully traverses these rejections.

In order for a reference to anticipate a claim under § 102, that reference must disclose every claimed limitation of the claim, either explicitly, or under the principle of inherency.

Applicant's claim 55 is directed to an assembly for fixing a tube to a patient's mouth that includes a tube clamping means and a securing means. The tube clamping means further includes a first positioning means, a first tube clamping member, a second tube clamping member, and a means for hingeable movement connecting the first and second tube clamping members, such that the second clamping member is moveable between a closed position, in which the tube is clamped between the first and second clamping members **with the first clamping member extending under the tube**, and an open position. The second clamping member extends above the tube when in a closed position, and its movement is over and above the tube being clamped. This movement of the second clamping member can be accomplished without movement of the first clamping member relative to the second clamping member.

Rogers is directed to a tube positioner wherein the tube clamping member that extends below the tube is moveable relative to the upper, fixed, tube clamping member. This

clearly differs from the assembly claimed in Applicant's claim 55, in which it is the upper (second) clamping member that is moveable with respect to the lower (first) clamping member ("with the first tube clamping member extending under the tube"). Since Rogers does not disclose or suggest this claimed feature of Applicant's claim 55 (and in fact teaches away therefrom), Rogers does not anticipate Applicant's claim 55. Reconsideration and withdrawal of this rejection are respectfully requested.

Applicant's claim 85 is directed to a method of fixing a tube to the mouth of a patient. The method includes providing the assembly of claim 55, and clamping the tube in the clamping means by moving the second (upper) clamping member between an open position and a closed position while the first (lower) clamping member is fixed to the first positioning means. As stated previously, the tube positioning device disclosed by Rogers includes a lower clamping means that is moveable relative to the upper clamping means. The upper clamping means of Rogers cannot move in the manner of Applicant's second clamping member, as claimed in claim 85. Thus, Rogers does not disclose all of the claimed features of Applicant's claim 85, since Rogers does not disclose all of the features of the device claimed in Applicant's claim 55, and because the device disclosed in Rogers cannot function in the manner claimed in Applicant's claim 85. Reconsideration and withdrawal of this rejection are respectfully requested.

Nestor is directed to a tube holder that includes a pair of cylindrical bosses that extend outward from a base plate, each of which further includes a tangential arm extending downward and terminating at a hinge 16 connecting to one of a pair of arcuate shaped jaws. The arcuate jaws are in turn connected by another hinge 20 between the hinges 16. Each of the pair of arcuate shaped jaws pivots about its respective hinge 16 and the connecting hinge 20 from an open position to a closed position.

The Examiner takes the position that a user could hold one of the pair of arcuate jaws in place and merely pivot the other jaw during the clamping action. By taking this position, the Examiner is respectfully believed to be reading far more into Nestor's disclosure than one skilled in the art would be able to understand from it. Moreover, this interpretation ignores a

main purpose of Applicant's invention, which is to provide a device that enables fixation of a tube to a patient's head while allowing the tube to be left undisturbed during the fixation action. If a user were to hold one arcuate jaw relative to the base plate during movement of the other arcuate jaw, the user would need to use both hands and use the patient's head as a support in order to counter the forces exerted on the other arcuate jaw during the opening and closing of the clamp.

Furthermore, the geometry of the base plate, the arcuate jaws and the tangential arms of the cylindrical bosses that connect to the jaws does not permit sole movement of one jaw while preventing movement of the other jaw with respect to the base plate. In addition, Nestor does not disclose or suggest a first clamping member on which the tube finds support both before and after closing, as claimed in Applicant's claim 55. Since Nestor does not disclose or suggest all of the elements of Applicant's claim 55, Nestor does not anticipate Applicant's claim 55. Reconsideration and withdrawal of this rejection are respectfully requested.

Claims 56, 67-71, 75, and 81-84 all depend from claim 55, and are all thus patentable for the same reasons as claim 55. Reconsideration and withdrawal of these rejections are respectfully requested.

The §103 Rejections

The Examiner rejected claims 72-74 under U.S.C. § 103(a) as being obvious over Rogers in view of United States Patent No. 6,067,985 (Islava), or, alternatively, as being obvious over Nestor in view of Islava. The Examiner further rejected claims 76, and 79-80 under 35 U.S.C. § 103(a) as being as being obvious over Rogers in view of WO 97/48432 (Russo), or, alternatively, as being obvious over Nestor in view of Russo. The Examiner also rejected claim 82 under U.S.C. § 103(a) as being obvious over Rogers in view of Nestor, and, finally, rejected claim 85 under U.S.C. § 103(a) as being obvious over Nestor.

Applicant respectfully traverses these rejections.

Applicant first notes that claims 72-74, 76, 79-80, and 82 all depend from claim 55, and are all thus patentable for the same reasons as claim 55. Reconsideration and withdrawal of these rejections are respectfully requested.

With regard to claim 85, Applicant urges that the Examiner has failed to establish a *prima facie* case of obviousness. In order to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify or combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the combination of the prior art references must teach or suggest all claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must be found in the prior art, and not be based on the Applicant's disclosure.

The Examiner takes the position that the device disclosed in Nestor can perform the clamping method claimed in Applicant's claim 85. However, as discussed above in traversing the Examiner's §102 rejection based on Nestor, it is unrealistic and impossible to open and close Nestor's clamp and holding one jaw stationary with respect to the base plate and moving only the other jaw, as claimed in Applicant's claim 85. The Examiner's position is respectfully an application of hindsight. Thus, there is no suggestion or motivation to modify the clamping method of Nestor in the manner claimed by Applicant's claim 85, nor is there any reasonable expectation of success in so modifying Nestor's clamping method. Finally, Nestor's clamping method does not disclose all of the claimed features of Applicant's claim 85, and Nestor's device does not include all of the claimed elements of Applicant's claim 55. Therefore, Applicant's claim 85 is not obvious over Nestor. Reconsideration and withdrawal of this rejection are respectfully requested.

CONCLUSION

Applicant urges that claims 55-85, as amended, are in condition for allowance. Early and favorable action is earnestly solicited. If the Examiner believes that issues can be resolved

through a telephone interview, the Examiner is urged to call the undersigned at the telephone number listed below.

Respectfully submitted,

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Attachment A

Claims showing changes

60. (Once Amended) The assembly according to claim [56] 58, wherein each of the attachment straps is connected to the plate at a plurality of locations and has a recess between the plurality of locations.

63. (Once Amended) The assembly according to claim 57, wherein the slots are [disposed] disposable at a level with corners of a jaw of the patient with the assembly fixing the tube to the patient's mouth.

66. (Once Amended) The assembly according to claim 64, wherein the cap [extends] is extendible over the patient's head with the assembly fixing the tube to the patient's mouth, the cap comprising means for attachment of care or monitor lines at a front or upper side thereof.

67. (Once Amended) The assembly according to claim 55, wherein the means for hingeable movement provides for hingeable movement for the second tube clamping member about an axis that is substantially parallel to the tube [with the tube disposed] when the tube is received in the tube clamping means.

73. (Once Amended) The assembly according to claim 72, wherein the slots are [vertically] aligned.

75. (Once Amended) The assembly according to claim 56, wherein the positioning plate [conforms] is conformable to the patient's face.